



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60Day-22-0573; Docket No. CDC-2022-0041]**

**Proposed Data Collection Submitted for Public Comment and Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC),  
Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on an information collection project titled National HIV Surveillance System (NHSS). The NHSS is designed to collect information on cases of human immunodeficiency virus (HIV) and indicators of HIV disease and HIV disease progression including AIDS. Data is used to monitor the extent and characteristics of the HIV burden in the United States.

**DATES:** CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2022-0041 by either of the following methods:

- Federal eRulemaking Portal: [Regulations.gov](https://www.regulations.gov). Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS H21-8, Atlanta, Georgia 30329.

**Instructions:** All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to [regulations.gov](https://www.regulations.gov).

Please note: Submit all comments through the Federal eRulemaking portal ([regulations.gov](https://www.regulations.gov)) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS H21-8, Atlanta, Georgia 30329; phone: 404-639-7118; E-mail: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of

information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and

5. Assess information collection costs.

#### Proposed Project

National HIV Surveillance System (NHSS) (OMB Control No. 0920-0573, Exp. 11/30/2022) - Revision - National Center for HIV,

Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

### Background and Brief Description

CDC is authorized under Sections 304 and 306 of the Public Health Service Act (42 USC 242b and 242k) to collect information on cases of human immunodeficiency virus (HIV) and indicators of HIV disease and HIV disease progression, including AIDS. Data collected as part of the National HIV Surveillance System (NHSS) are the primary data used to monitor the extent and characteristics of the HIV burden in the United States. HIV surveillance data are used to describe trends in HIV incidence, prevalence and characteristics of persons diagnosed with HIV infection and used widely at the federal, state, and local levels for planning and evaluating prevention programs and health-care services, allocating funding for prevention and care, and monitoring progress toward achieving national prevention goals of the Ending the HIV Epidemic in the U.S. initiative.

NHSS data collection activities are currently supported through cooperative agreements with health departments under CDC funding Opportunity Announcements PS18-1802: Integrated HIV Surveillance and Prevention Programs for Health Departments and PS20-2010 Integrated HIV Programs for Health Departments to Support Ending the HIV Epidemic in the United States. The activities funded under these announcements promote and support

improving health outcomes for persons living with HIV through achieving and sustaining viral suppression, and reducing health-related disparities by using quality, timely, and complete surveillance, and program data to guide HIV prevention efforts toward reducing new HIV infections and ending the HIV epidemic in the United States.

The Division of HIV Prevention (DHP), National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), CDC in collaboration with health departments in the states, the District of Columbia, and U.S. dependent areas, conducts national surveillance for cases of HIV infection that includes critical data reported across the spectrum of HIV disease stages from HIV diagnosis to death. The systematic data collection provides the essential data used to calculate population-based HIV incidence estimates, describe the geographic distribution of disease, monitor HIV transmission and drug resistance patterns and genetic diversity of HIV among infected persons, detect and respond to HIV clusters of recent and rapid transmission, and monitor perinatal exposures. NHSS data are also used locally to identify persons with HIV who are not in medical care and linking them to care and needed services. NHSS data continue to be collected, maintained, and reported using standard case definitions, report forms and software. The system is periodically updated as needed to keep pace with changes in testing technology and advances in HIV care and treatment, as

well as changing prevention program monitoring and evaluation needs.

The revisions requested in this package include program-initiated modifications to currently collected data elements and forms including changes to the Adult Case Report Form (ACRF), the Pediatric Case Report Form (PCRF) and the Perinatal HIV Exposure Reporting (PHER) form. We request approval to continue data collection using our currently approved data collection instruments through December 2022 and implement the proposed form changes starting in January 2023. Changes made to both the ACRF and PCRF include addition of two variables to collect sexual orientation information, updated gender identity response options, addition of two new HIV test types to accommodate changes in testing technology, addition of two new response options related to self-testing, addition of three new HIV testing history variables to summarize self-testing activities (ACRF only) and formatting changes to improve usability of both forms. The main changes to the PCRF include those related to critical perinatal exposure information that was consolidated across the PHER and PCRF to reduce redundancy across forms and include some new and revised data elements needed to assess progress with perinatal elimination efforts and support HIV prevention activities. Combining the PCRF and PHER forms reduced the total number of pages of information collected from two forms with eight total pages to one form with six pages which will reduce burden of data collection and increase usability of

the forms. In all, 10 variables in the PHER form will no longer be collected; seven variables from the PHER form were combined with existing variables on the PCRF; 13 variables were moved from the PHER form to the new PCRF; five new variables were added to the PCRF including four related to breastfeeding/chestfeeding and premastication risk behaviors and one variable related to documentation of laboratory results in a person's labor and delivery record; response options for the existing delivery method variable was revised on the PCRF to align with current medical practices. Health departments will now use the one revised PCRF form to report perinatal exposures and pediatric case reports and the revised burden for both perinatal exposure reporting and pediatric case reporting is now combined and included under the PCRF form line. The number of respondents reporting pediatric case reports is 59 and a subset of those jurisdictions that have perinatal exposure reporting will also report some perinatal exposure information using the revised PCRF form and the PCRF burden estimate has been revised to account for this reporting. The time per response for the PCRF has been revised from 20 minutes to 35 minutes on average per response to reflect these changes and increased reporting of perinatal exposure data elements. HIV Incidence data collection as anticipated in the previous revision was not implemented and is being discontinued as a separate activity. HIV incidence continues to be estimated by CDC via statistical methods. No other revisions to the other data collection forms for this ICR

are proposed. Burden estimates have been updated to reflect the discontinuation of incidence data collection, discontinued use of the PHER form for perinatal exposure reporting, and revised PCRF which will be used for both perinatal exposure reporting and pediatric case reporting. In addition, the revised burden estimate includes small increases in burden for case and laboratory updates, deduplication activities and case investigations due to the increasing number of persons living with HIV for which additional laboratory and case information is reported and linkage to care activities are conducted. The burden estimates for case reports decreased slightly since the last OMB approval due to decreases in adult and pediatric HIV diagnoses reported.

CDC provides funding for 59 jurisdictions to provide adult and pediatric HIV case reports. Additional information on perinatal exposures is also reported in a subset of jurisdictions when reportable using the same pediatric case report form and used to monitor progress toward perinatal HIV elimination goals. Health department staff compile information from laboratories, physicians, hospitals, clinics, and other health care providers to complete the HIV adult and pediatric case reports. CDC estimates that approximately 789 adult HIV case reports and 57 perinatal exposure and pediatric case reports are processed by each health department annually.

These data are recorded using standard case report forms either on paper or electronically and entered into the



electronic reporting system. Updates to case reports are also entered into the reporting system by health departments as additional information may be received from laboratories, vital statistics, or additional providers. Evaluations are also conducted by health departments on a subset of case reports (e.g. re-abstraction, validation). CDC estimates that on average approximately 85 evaluations of case reports, 2519 updates to case reports and 10130 updates of electronic laboratory test data will be processed by each of the 59 health departments annually. In addition, all 59 health departments will conduct routine deduplication activities for new diagnoses and cumulative case reports. CDC estimates that health departments on average will follow-up on 3032 reports as part of deduplication activities annually. Case report information compiled over time by health departments is then de-identified and forwarded to CDC on a monthly basis to become part of the national HIV surveillance database.

Additional information will be reported by health departments for monitoring and evaluation of health department investigations including activities identifying persons who are not in HIV medical care and linking them to HIV medical care (e.g., Data-to-Care activities) and other services and identifying and responding to clusters. CDC estimates health departments will on average process 929 responses related to investigation reporting and monitoring annually.

Clusters of HIV are groups of persons related by recent, rapid transmission, for which rapid response is needed in order to intervene to interrupt ongoing transmission and prevent future HIV infections. Health departments may detect clusters through multiple means, including through routine analyses of Surveillance data and other data reported to the NHSS. Data on clusters of recent and rapid HIV transmission in the United States will be collected to monitor situations necessitating public health intervention, assess health department response, and evaluate outcomes of intervention activities. These summary data will be collected through quarterly cluster report forms that will be completed by health departments for clusters that they have identified and for which they are actively conducting response activities. Health departments with detected clusters will complete an initial cluster report form when a cluster is first identified, a cluster follow-up form for each quarter in which the cluster response remains active and a cluster close-out form when cluster response activities are closed or at annual intervals while a cluster response remains active. CDC estimates on average health departments will provide information for 2.5 cluster initial cluster reports, five Cluster Follow-up Form reports, and 2.5 Cluster Close-out Form reports annually.

The Standards Evaluation Report (SER) is used by CDC and Health Departments to improve data quality, interpretation, usefulness, and surveillance system efficiency, as well as to monitor progress toward meeting surveillance program objectives.

The information collected for the SER includes a brief set of questions about evaluation outcomes and the collection of laboratory data that will be reported one time a year by each 59 health departments.

CDC requests OMB approval for an estimated 60731 annual burden hours in this Revision. There are no costs to respondents other than their time to participate.

#### Estimated Annualized Burden Hours

| Type of Respondent | Form Name   | Number of Respondents | Number of Responses per Respondent | Average Burden per Response (in hr) | Total Burden (in hr) |
|--------------------|---|-----------------------|------------------------------------|-------------------------------------|----------------------|
| Health Departments | Adult HIV Case Report (ACRF)                            | 59                    | 789                                | 20/60                               | 15517                |
| Health Departments | Perinatal Exposure and Pediatric HIV Case Report (PCRF) | 59                    | 57                                 | 35/60                               | 1962                 |
| Health Departments | Case Report Evaluations                                 | 59                    | 85                                 | 20/60                               | 1672                 |
| Health Departments | Case Report Updates                                     | 59                    | 2519                               | 2/60                                | 4954                 |
| Health Departments | Laboratory Updates                                      | 59                    | 10130                              | 0.5/60                              | 4981                 |
| Health Departments | Deduplication Activities                                | 59                    | 3032                               | 10/60                               | 29815                |
| Health Departments | Investigation Reporting and Evaluation                  | 59                    | 929                                | 1/60                                | 914                  |
| Health Departments | Initial Cluster Report Form                             | 59                    | 2.5                                | 1                                   | 148                  |

|                       |   |    |     |     |       |
|-----------------------|---|----|-----|-----|-------|
| Health<br>Departments | Cluster Follow-up<br>Form                                   | 59 | 5   | 0.5 | 148   |
| Health<br>Departments | Cluster Close-out<br>Form                                   | 59 | 2.5 | 1   | 148   |
| Health<br>Departments | Annual<br>Reporting:Standards<br>Evaluation Report<br>(SER) | 59 | 1   | 8   | 472   |
| Total                 |   |    |     |     | 60731 |

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